Multitak SS
FROM BONUTTI RESEARCH

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OCT 2 9 2001

Bonutti Research, Inc.
Multitak Splinter 3.0 mm Resorbable Anchor
510(k) Premarket Notification

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is submitted in accordance with the requirements of 21 CFR 807.92:

Contact Person: Patrick Balsmann, MS, RAC,
Director, Regulatory/Clinical Affairs & QA
Bonutti Research, Inc.,
P.O. Box 1367, Effingham, Illinois 62401
Phone: 217.342.3412, ext. 321

Date Prepared: July 31, 2001

Proprietary Name: Multitak Splinter 3.0 mm Resorbable Anchor

Common Name: Resorbable Soft Tissue Anchor

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue.

Device Description: The Multitak Splinter 3.0 mm Resorbable Anchors are cylindrical suture anchors with a conical tip on one end. The resorbable anchors are injection molded from a poly-L-lactic acid resin and have two transverse suture holes. The resorbable implant comes threaded with up to USP Size No. 2 polyester suture preloaded on the tip of a single use disposable introduction device. The resorbable implant and suture is delivered into a predrilled bone site. The suture ends are pulled to engage cancellous bone and to toggle and lock the anchor in bony tissue. A curved needle attached to the suture end is used to secure soft tissue to bone.

Intended Use: The Multitak Splinter 3.0 mm Resorbable Anchor System consists of a single use bone soft tissue resorbable anchor implant and is intended for use as a load bearing or non-load bearing suture anchor in the attachment of soft tissue to bone in various arthroscopic and open orthopedic procedures.

The Multitak Splinter 3.0 mm Resorbable Anchors are indicated for use in the following orthopedic soft tissue to bone fixation applications:

Shoulder:
- Bankart lesion repairs
- Acromio-clavicular repairs
- Deltoid repairs
- Rotator cuff tear repairs
- Biceps tenodesis

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Elbow:	Ulnar or radial collateral ligament reconstruction
Knee:	Extra-capsular repairs Medial collateral ligament repair Lateral collateral ligament repair Posterior oblique ligament repair Illiotibial band tenodesis Patellar tendon repair VMO advancement Joint capsule closure
Foot/Ankle:	Medial/Lateral repairs/reconstructions Achilles tendon repairs

Predicate Device(s): The Multitak Splinter 3.0 mm Resorbable Anchors are similar in intended use and materials to current commercially available poly-L-lactic acid resorbable implants including the Mitek 3.5 mm Panalok Wedge Absorbable Suture System. The Multitak resorbable implants are similar in design and intended use to existing Multitak suture anchors determined to be substantially equivalent by FDA.

Predicate Comparison: Performance testing comparing the mechanical strengths and failure modes of the Multitak Splinter 3.0 mm Resorbable Anchors to predicate devices demonstrated that the anchors are statistically equivalent.

Submitted by:

Patrick Balsmann
Director, Regulatory/Clinical Affairs & QA

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2001

Mr. Patrick Balsmann
Director, Regulatory/Clinical Affairs
and Quality Assurance
Bonutti Research, Inc.
P.O. Box 1367
Effingham, Illinois 62401

Re: K012465
Trade/Device Name: Multitak Splinter 3.0 mm Resorbable Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastner
Regulatory Class: Class II
Product Code: HWC, MAI
Dated: July 31, 2001
Received: August 1, 2001

Dear Mr. Balsmann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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FROM BONUTTI RESEARCH

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Bonutti Research, Inc. – Multitak Splinter 3.0 mm Resorbable Anchor
510(k) Premarket Notification

INDICATIONS FOR USE

Device Name: Multitak Splinter 3.0 mm Resorbable Anchor.

Indications for Use: The Multitak Splinter 3.0 mm Resorbable Anchor System consists of a single use bone soft tissue resorbable anchor implant and is intended for use as a load bearing or non-load bearing suture anchor in the attachment of soft tissue to bone in various arthroscopic and open orthopedic procedures.

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for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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